

REMARKS

Summary of the Office Action

Claims 1-23 are pending in this application.

Claims 3, 4, 9, 10, 13, 14, 19, and 20 are withdrawn from consideration.

Claims 1, 2, 5-8, 11, 12, and 23 are rejected under 35 U.S.C. § 102(b), as anticipated over Yan, United States Patent No. 5,843,172 ("Yan").

Claims 15-17 are rejected under 35 U.S.C. § 103(a), as obvious over Globerman et al., International Patent No. 96/26682 ("Globerman") in view of Brown et al. United States Patent No. 6,071,305 ("Brown").

Claim 21 is rejected under 35 U.S.C. § 103(a), as obvious over Globerman in view of Leone et al., United States Patent No. 5,882,335 ("Leone").

Claim 22 is rejected under 35 U.S.C. § 103(a), as obvious over Globerman in view of obvious matters of design choice.

Claim 15 and 18 are rejected under 35 U.S.C. § 103(a), as obvious over Tower et al., European Patent No. EP 1057460 ("Tower") in view of Globerman and Brown.

Applicant's Response

Applicant respectfully traverses the rejections set forth in the Final Action as having been prompted by hindsight reconstruction of the invention from disparate elements found in the prior art. The existence of the newly-cited patent to Yan, in fact confirms the non-obviousness of the combining a hollow tubular stent as taught in Globerman with the bioabsorbable

coating of Brown. Applicant therefore traverses the obviousness rejections based on Globerman and Brown, Leone and/or Tower.

In particular, applicant has amended claims 1, 15 and 23 to patentably distinguish over Yan. Applicant respectfully submits that the claims as previously presented distinguished over the prior art. Nevertheless, in the interests of advancing prosecution of this application, applicant has amended each of claims 1, 15 and 23 to recite that the claimed implantable device comprises a **"tubular member having a substantially continuous internal lumen of uniform cross-section and a multiplicity of pores in fluid communication with the lumen."** Support for this recitation is provided in the specification, for example, at page 7, lines 21-29 and Figures 1-4. Moreover, the definition of a "tube" is "a hollow cylinder, especially one that conveys a fluid or functions as a passage." See, e.g., the definition of "tube" at www.dictionary.com.

In rejecting claims 1 and 23 as anticipated by Yan, the Office action states that "Fig. 2 shows a stent 20 formed of a tubular member with a lumen therein and a multiplicity of pores 18 in fluid communication with the lumen...." Applicant respectfully disagrees. The device shown in FIG. 2 of Yan and described in the accompanying written description comprises a sintered metal wire. See generally, Yan Col. 3, line 55 to Col. 4, line 65. In particular, sintering is described as "a process of fabrication where particles are bonded together without entirely melting the particles." Col. 4, lines 2-4. As a result, "[g]aps 26 exist between each particle despite the fact that the particles are pressurized and are in contact with adjacent particles ... When the metal is heated to slightly below the melting point of the metal, the particles bond with neighboring particles. **The gaps in the packed lattice form pores 18 when the particles are sintered.**" Col 4, lines 15-23.

Thus, while the sintered metal wire shown in FIG. 2 of Yan has a multiplicity of pores, those pores do not constitute a "tubular member" having a "substantially continuous lumen of uniform cross-section".

Applicant submits that the sintered metal wire described in Yan is a fundamentally different structure than the tubular member recited in claims 1, 15 and 23. The present application repeatedly distinguishes a "lumen" from a "pore" throughout the specification, such as on page 5, lines 8-12 which read, "[t]he therapeutic agent is retained within the stent during delivery, and exits **from the lumen** into the vessel **through the multiplicity of pores**, over an extended period of time, after the stent is deployed in a patient's vessel."

Yan therefore does not teach or suggest a stent formed from a "tubular member having a substantially continuous internal lumen of uniform cross-section and a multiplicity of pores in fluid communication with the lumen." Because Yan does not teach or describe the claimed structure, it does not anticipate any of claims 1, 15 or 23. Moreover, because the stent disclosed in Yan apparently would provide satisfactory performance, although manufactured by a substantially different process, there would have been no motivation for one of ordinary skill to have modified that device by substituting a conventional sold-wall tubular member for the specially designed sintered component described in Yan. Accordingly, the claimed invention is not obvious in view of the teachings of Yan, which instead suggest an entirely different approach to achieving the objective of long-term drug elution from a stent.

With respect to the Section 103 rejections based upon Globerman in view of Brown, Leone or Tower, applicant submits that those references, taken in combination, neither teach nor suggest the invention described in pending claims. Claim 15

requires, among other things, "loading the therapeutic agent and biodegradable polymer into the lumen, wherein the therapeutic agent is formulated to be retained within the lumen during delivery of the stent and thereafter eluted within the vessel with a rate controlled by biodegradation of the bioabsorbable polymer."

Globerman does not teach or suggest that the delivery of the therapy agent may be controlled by biodegradation of a bioabsorbable polymer. Instead, Globerman states that "the lumen of the tubular material may contain radiopaque material or pharmacological substance" and that "[t]he wall of the tubing may have one or more small or miniature openings so that such pharmacological substances can be dispersed." Globerman nowhere teaches or suggests that a therapeutic agent be dispersed within a biodegradable polymer such that the rate of release of the agent is controlled **by the rate of biodegradation of the polymer**, as opposed to **the size of the openings**.

The Office action relies on Brown to cure this deficiency in Globerman, citing the language, "As illustrated in the embodiment of the present invention shown in FIG. 4, the cavity 20 preferably contains a biocompatible delivery matrix 27 containing a biologically active agent for release. Such an exemplary delivery matrix 27 may be a biodegradable or non-biodegradable material." While Brown discusses the use of a biocompatible delivery matrix containing a biologically active agent for release, Brown does not teach or suggest that therapeutic agent is "eluted within the vessel with a rate **controlled by** biodegradation of the bioabsorbable polymer", as required by claim 15. Instead, Brown appears to rely on geometrical constraints to control the rate of delivery, as shown by the following statements:

"Furthermore, the *size and shape of the cavity 20* may be varied to **control** the total amount of active agent 23 which is delivered and the rate of delivery. *The size of the delivery means or fluid opening*, which is a slit shaped opening 22 in the embodiment of the present invention illustrated in FIG. 3 can also be varied to **control** the rate of delivery of the active agent 23." Col. 8, lines 26-33;

"The size and number of the holes 28 may be varied to **control** the rate of delivery of the active agent from the stent 11"." Col. 9, lines 30-31;

"The size of the fluid inlet opening 48 may be varied to **regulate** the delivery rate of the active agent 23 by **controlling** the rate at which the fluid enters and swells the osmotic agent 44." Col. 10, lines 33-36; and

"The number and size of the openings 52, 54 may be varied to **regulate** the delivery rate of the active agent 23." Col 10, lines 64-65.

The foregoing passages make plain that neither Globerman and Brown, teach or suggest dispersing a therapeutic agent within a biodegradable polymer to control the rate of release of the therapeutic agent, as opposed to controlling the size and shape of the openings through which the therapeutic agent is released. Applicant submits that the motivation to modify the combination of Globerman and Brown to arrive at the claimed invention impermissibly comes from only a single source - applicant's own disclosure.

The addition of Tower to the teaching of Globerman or even the combination of Globerman and Brown does not cure the above-described deficiency. As noted at page 4 of the Office

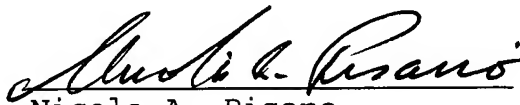
action, *Tower provides no teaching relevant to drug eluting stents*. Given the above distinctions between the pending claims and the cited art, applicant respectfully submits that independent claims 1, 15 and 23 patentably distinguish over the prior art of record. Accordingly, dependent claims 2, 5-8, 11, 12, 16, 18 and 21-22 are patentable for at least the same reasons.

In addition, because claims 1 and 15 are generic to all of the disclosed embodiments, withdrawn claims 3, 4, 9, 10, 13, 14, 19 and 20 also should be rejoined in this case.

CONCLUSION

In view of the foregoing, applicant respectfully submits that the application is in condition for allowance. An early and favorable action is earnestly requested.

Respectfully submitted,



Nicola A. Pisano
Registration No. 34,408
Attorney for Applicant

c/o Luce, Forward,
Hamilton & Scripps, LLP
11988 El Camino Real, Suite 200
San Diego, California 92130
Tel.: 858.720.6320